Louisiana Medicaid
Tolvaptan (Samsca®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for tolvaptan (Samsca®).

Additional Point-of-Sale edits may apply.

*Samsca® has a **Black Box Warning**. Please refer to prescribing information for details.*

Approval Criteria

- The recipient is 18 years of age or older on the date of the request; **AND**
- Tolvaptan (Samsca®) is **NOT** being used to treat autosomal dominant polycystic kidney disease (ADPKD), which is **stated on the request**; **AND**
- The recipient has **ONE** of the following which is **stated on the request:**
    - *hypervolemic* hyponatremia; **OR**
    - *euvolemic* hyponatremia; **AND**
- The recipient's hyponatremia is clinically significant and is defined as **ONE** of the following which is **stated on the request**:
    - Serum sodium <125 mEq/L; **OR**
    - Less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction; **AND**
- Treatment with tolvaptan (Samsca®) was initiated or re-initiated in a hospital setting [this is **stated on the request**]; **AND**
- The recipient has received less than 30 days of therapy [number of hospital-administered doses is **stated on the request**]; **AND**
- Tolvaptan (Samsca®) has been prescribed by, or in consultation with, a nephrologist, cardiologist, or endocrinologist; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The maximum dose of 60 mg daily will not be exceeded; **AND**
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of approval: 1 to 29 days, not to exceed a total of 30 days duration of **treatment**. Duration of approval is contingent on number of days of treatment in a hospital setting.

Reference

Samsca (tolvaptan) [package insert]. Rockville, MD: Otsuka America Pharmaceutical Co., Ltd; June 2018. https://www.otsuka-us.com/media/static/Samsca-PI.pdf?_ga=2.183944366.940455366.1579118528-1484128712.1579021165

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